DECLARATION OF CARSTEN ANDERSEN UNDER 37 C.F.R § 1.132

Corrected Version of my May 26, 2011 Declaration

I, Carsten Andersen, declare as follows:

1. I am a citizen of Denmark and presently reside in Vejle, Denmark.

2. I am over the age of twenty one, competent to testify in a court of law, and could and would testify to the matters set out below before the USPTO if required to do so.

3. I understand that this declaration is to be used to assist the prosecution of US Patent Application 10/581,628, of which I am the inventor.

4. I graduated from the Technical University of Denmark in January 1970 as Master of Science in Chemical Engineering.

5. I have been employed by Fertin Pharma A/S since 1983, and currently hold the position of Senior Scientist, Product Development. I am active in research and development activities relating to medicated chewing gums, and in particular nicotine gum.

6. I have read and understood US 6,586,449 B1 (Walling). I understand that it discloses a method of manufacturing a nicotine composition which comprises the steps:
   - Mixing a aqueous organic polyol with a certain cation exchange resin;
   - Admixing nicotine; and
   - Removing water.

7. The method of my invention differs from the Walling method in that the components are combined in a different order. The nicotine is combined with the cation exchange resin before the polyol is added.

8. According to Walling, its nicotine compositions have a nicotine release in the range 71-77% (see table 1 of Walling). Different release rates are obtained with different polyols. The release amounts are measured using the procedure of USP Official Monograph, Volume 25, pages 1225 and 1226 (see column 3, lines 51-56 of Walling).

9. Fertin Pharma A/S has conducted trials on the nicotine compositions produced by the method of my invention.

10. In 2009, two experimental scale runs each produced several batches of a nicotine composition according to my invention. These were labelled runs "A" and "B". Both used the addition method outlined in US Patent Application 10/581,628.

11. Run A was produced in a Stephan mixer, and used the following components in the following weight amounts. The order of addition of the ingredients is indicated by the numbering in the below table. After mixing of all components was complete, water was removed by heating to yield a powder.

Order	*Component*	*Amount (kg)*
1.	Purified Water	2.00
2.	Nicotine, Pharmaceutical grade	1.08
	Purified Water	1.00
3.	Cation Exchange Resin	4.32
4.	Glycerol, USP	1,80
	Purified Water	8.75

12. Run B was produced in a Diosna VAC20 mixer. The following components in the following weight amounts were used. The order of addition of the ingredients is indicated by the numbering in the below table. After mixing of all components, water was removed by heating to yield a powder.

Order	*Component*	*Amount (kg)*
1.	Purified Water	5.00
2.	Nicotine, Pharmaceutical grade	0.60
	Purified Water	0.50
3.	Cation Exchange Resin	2.40
4.	Glycerol, USP	1.00
	Purified Water	0.50

13. In 2010, further tests were carried out on a large number of commercial full scale batches. This also used the order of addition of US Patent Application 10/581,628, and the same materials as those used in the two test runs A and B described above. I am not authorised to publically disclose the amounts of the various components used, as this is considered by Fertin Pharma A/S to be commercially sensitive information.

14. The powders obtained from the three runs were tested by Fertin Pharma A/S's quality control group to determine nicotine release. The release test used was that of USP Official Monograph, Volume 26, pages 1309 and 1310. This is also the test method referred to in US Patent Application 10/581,628. This test

method is identical to that defined in USP Official Monograph, Volume 25, pages 1225 and 1226 (which is used in the Walling reference).

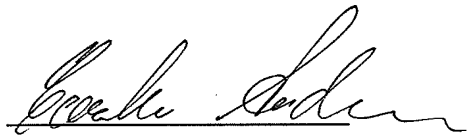
15. The average release results were 81.7% for run A and 80.2% for run B. The composition resulting from the full scale runs had an average release of 78.6%. These test results indicate an improvement in release relative to the data in Walling. Walling reports a 71% release for its example 1, which uses glycerol as the polyol (i.e. the same material as that used in Fertin Pharma A/S's experiments outlined above).

16. The fact that a nicotine release rate of 80% or greater could be obtained was unexpected and surprising. In order to obtain a release rate greater than 70% within 10 minutes, Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine. See Walling at col. 2, lines 56-58. Based on the teachings in Walling, I would not have expected that a nicotine release greater than the nicotine release values in Walling, much less nicotine release rates of 80% or greater, could be achieved by mixing the nicotine with the cation exchange resin prior to the polyol.

17. I have read and understood US 3,845,217 (Ferno). There is nothing in this document which suggests to me that the order of addition of the various components of a nicotine-resin product is important, let alone that this might have an influence on the release rate of the product. Therefore Ferno would not motivate the skilled reader of Walling to alter the order of addition of the ingredients used in Walling.

18. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Executed this 3 day of November, 2011 in Vejle, Denmark



Carsten Andersen